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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,358	PIEPER ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 23, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-42 and 44-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-42 and 44-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *February 1, 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' Response filed February 23, 2005, which cancelled claims 1-26 and 43, amended claims 27, 30-33, 35-39, 41-42 and 44, and added new claims 45-109.

Currently, claims 27-42 and 44-109 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.
>
> It does not identify the U.S. provisional application on which priority is claimed.

Drawings

The drawings are objected to because Figure 1 appears handwritten. In addition, the pictures of the gels in Figs. 3 and 4 have poor resolution. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not

be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, newly added claim 61 recites a modified sample having "improved characteristics." A modified sample having "improved characteristics" does not appear in the specification, as originally filed, and thus constitutes new matter.

Claims 27-42 and 44-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, the recitation of "plurality of components remains in the sample" is indefinite because it is not clear whether said "plurality of components" were in the sample prior to removing at least two specific predefined ligands. In addition, the recitation of "to be analyzed" is indefinite because it is not clear whether an analysis step is a required claim limitation. In addition, the duplicate recitations of "a plurality of components" is indefinite because it is not clear whether the two recited "plurality of components" reference the same plurality of components, or whether the two recited "plurality of components" reference two different pluralities of components.

In claims 32-33 and 103, the recitation of "proteins" lacks antecedent basis.

In claim 34, it is not clear how the step of "removing the bound ligands from the receptors" is incorporated into the method of claims 27 and 31. It is not clear whether/how the step of "removing the bound ligands from the receptors" is related to the step of recovering a modified sample, or whether the "ligands" contribute to "a plurality of components."

In claim 35, the recitation of "reusing" lacks antecedent basis because the step of using has not been recited.

In claims 39, 45, 52 and 60, the recitations of "remaining components in the modified sample" and "component remaining in the modified sample" lack antecedent bases.

In claim 41, the recitation of "removable from another receptor" is indefinite because it is not clear how one receptor is "removable" from another receptor when, according to claim 42, the two receptors appear to already be located in different locations.

In claim 59, the recitations of "the specific predefined receptors" and "ligands remaining in the modified sample" lack antecedent bases. In addition, the recitations of "selected" and "facilitate analysis" lack antecedent bases because the steps of selecting and facilitating analysis have not been recited.

In claim 61, the recitation of "improved characteristics" is indefinite because it is not clear what parameters constitutes "characteristics" or the mechanism or steps required for improvement.

In claims 98-100, the recitation of "additional components" lacks antecedent basis because a first "component" has not been recited.

In claim 101, the recitations of "allows quantitation" and "could be quantitated" are indefinite because it is not clear whether said recitations require one or more steps of quantitation.

In claims 105-107, the recitation of "one or more immunoglobulins" renders the scope of the Markush-type claims indefinite because it is not clear whether two or more immunoglobulins are each members of the Markush group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-42, 44-62, 98-105 and 108-109 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens & Yip (US 6,225,047).

Hutchens & Yip describe a method for separating ligands (see col. 34, lines 9-42) from a sample (see col. 33, lines 54-67) and recovering a modified sample (see col. 36, lines 52-67) comprising the steps of: removing at least two (see col. 3, lines 57-61) (see col. 36, lines 59-60, "un-desired analytes" (emphasis added)) specific predefined (see col. 36, line 56-57, "The absorbents are selected...") ligands.

With respect to claims 28-29, Hutchens & Yip describe a method wherein at least four ligands are removed (see Example VII, Fig. 19).

With respect to claims 32-33 and 103, Hutchens & Yip describe a method wherein at least 75% by weight of all proteins in a sample are removed (see col. 36, line 54, "extract all but a desired analyte", see e.g. col. 34, lines 9-23, "Specific examples of analytes... metal ions", see col. 52, line 53, "serum").

With respect to claim 34, Hutchens & Yip describe a method further comprising the step of removing the bound ligands from the receptors (see col. 63, lines 39-41, "laser desorption").

With respect to claims 35-38, Hutchens & Yip describe a method further comprising the step of repeating the method by reusing the receptors with a new sample (see col. 37, lines 33-58, Fig. 3).

With respect to claims 39 and 102, Hutchens & Yip describe a method further comprising the step of separating and quantifying the remaining components in the modified sample (see col. 36, line 61, "desorption spectrometry").

With respect to claims 40-41, Hutchens & Yip describe a method wherein an immobilized receptor is selectively removable from another immobilized receptor (see col. 8, lines 3-13).

With respect to claims 45-59, 61 and 99, Hutchens & Yip describe a method further comprising the step of analyzing at least one component remaining in the modified sample by mass spectrometry (see col. 36, line 61, "desorption spectrometry").

With respect to claim 60, Hutchens & Yip describe a method further comprising the step of concentrating components remaining in the modified sample (see col. 63, line 30, "allowed to concentrate").

With respect to claim 62, Hutchens & Yip describe a method wherein at least one specific predefined ligand is present at higher abundance than at least one of the plurality of components remaining in the sample after removal of the specific predefined ligand (compare Fig. 19A versus 19B, Fig. 19A versus 19C, etc.).

With respect to claim 98, Hutchens & Yip describe a method wherein at least 100 components remaining in the sample are analyzed (see Fig. 19).

With respect to claims 100-101, Hutchens & Yip describe a method wherein the remaining components were not previously detectable (see col. 4, lines 31-37, "other separation and detections systems cannot match").

With respect to claim 104, Hutchens & Yip describe a method wherein at least one ligand is an immunoglobulin (see col. 5, line 19).

With respect to claim 105, Hutchens & Yip describe a method wherein at least two ligands are an immunoglobulin (see col. 5, line 19) and albumin (see col. 27, line 27).

With respect to claims 108-109, Hutchens & Yip describe a method further comprising the step of treating the sample with a glycosidase before or after sample modification (see col. 44, lines 17-20).

Claims 63-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et al. (US 6,632,655).

Mehta et al. describe a method for separating ligands (see col. 45, line 47, "expression products") from a sample (see col. 45, lines 35-40) and recovering a modified sample comprising the steps of: removing at least two specific predefined ligands (see col. 45, line 45, "subtractive hybridization") (see col. 49, lines 57-60, "library... can be used to screen... RNA, DNA"), recovering a modified sample comprising a plurality of remaining components (see col. 46, lines 41-42, "differentially expressed mRNA species"), wherein the removing step comprises the steps of contacting the sample with an affinity binding composition comprising:. a first and second solid phase matrix contacting each other (see Fig. 3B), an immobilized first receptor (see col. 5, lines 27-36) capable of specific binding to a first ligand but not a second ligand (see col. 2, lines 54-56, col. 7, lines 16-17), and an immobilized second receptor (see col. 5, lines 27-36) capable of specific binding to a second ligand but not the first ligand (see col. 2, lines 54-56, col. 7, lines 16-17).

With respect to claims 64, 66 and 68, Mehta et al. describe a method wherein the affinity binding compositions comprise a third receptor, fourth receptor, and fifth receptor (see col. 2, lines 54-56).

With respect to claims 70, 83, 85 and 92, Mehta et al. describe affinity columns (see Fig. 3B).

With respect to claims 71, 78, 86 and 93, Mehta et al. describe plurality of particles (see Fig. 3B).

With respect to claims 72, 79 and 87, Mehta et al. describe a method wherein the sets of particles are homogeneous (see col. 53, lines 6-12).

With respect to claim 73, Mehta et al. describe a method wherein the first receptor is not immobilized on the second solid phase matrix (see col. 2, lines 54-56, col. 7, lines 16-17).

With respect to claims 74-75, 80-81, 88-89 and 94-95, Mehta et al. describes a method wherein the affinity binding compositions comprise recombinantly produced (see col. 48, line 28) antibody receptors (see col. 5, lines 27-36).

With respect to claim 97, Mehta et al. describes a frit (see col. 14, line 49).

Claim Rejections - 35 USC § 103

Claims 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (US 6,632,655) in view of Ullman et al. (5,137,808).

Mehta et al. describe a method for separating ligands as substantially described supra. Mehta et al. do not teach a method wherein at least three of the ligands are listed in claims 106-107.

However, Ullman et al. teach the use of affinity binding compositions (see col. 6, lines 62-66) for isolating and characterizing blood plasma components, including albumin, transferrin, haptoglobin, alpha 1-antitrypsin, alpha 2-macroglobulin, apo A1 lipoprotein, globulins, and alpha acid glycoprotein (see col. 4, lines 27-44). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method for separating ligands, as taught by Mehta et al., with the use of compositions specific for blood plasma components because Ullman et al. discovered a convenient, on-site means for testing a variety of analytes (see col. 3, lines 11-14), including analytes that are clinically important (see col. 4, line 33-34).

Response to Arguments

In prior Office Action, Examiner objected to the declaration because the declaration does not identify the mailing address of each inventor and does not identify the U.S. provisional application on which priority is claimed. Examiner acknowledges Applicants' request to hold this objection in abeyance.

In prior Office Action, claims 27, 35-38, 41-42 and 44 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for various reasons. Applicants have amended the affected claims to obviate these rejections. Accordingly, these rejections are withdrawn.

In prior Office Action, claims 27-42 and 44 were rejected under 35 U.S.C. 102(b) as being anticipated by Wheatley, 603 J. CHROMATOGR. 273 (1992). In addition, claims 28-29 and 40-42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wheatley, 603 J. CHROMATOGR. 273 (1992) in view of Lackie (US 5,372,783). In a telephone interview held on January 26, 2005, agreement was reached that Wheatley no longer anticipated Applicants' claims, as amended. Specifically, Wheatley does not teach a modified sample comprising a plurality of components. In light of said telephone interview, and in light of new rejections in view of Hutchens & Yip (US 6,225,047) and Mehta et al. (US 6,632,655), set forth supra, the prior art rejections in view of Wheatley are withdrawn. Discussion pertaining to Wheatley is considered moot.

In prior Office Action, claims 27-42 and 44 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 27-42 and 44 of copending Application No. 10/250,898. Applicants point out that a Restriction Requirement was made in copending Application No. 10/250,898. Accordingly, this rejection is withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
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